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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/692,249	10/19/2000	Richard Gareth Warner	4-30476B/C1C1	6806

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EXAMINER

GUCKER, STEPHEN

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 08/14/2002

5

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/692,249

Applicant(s)

Warner

Examiner

Stephen Gucker

Group Art Unit

1647

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 4/24/02
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-22 is/are pending in the application.
- Of the above claim(s) 11-16 + 20-21 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-3 + 22 is/are rejected.
- ☒ Claim(s) 4-10 + 17-19 is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

Art Unit: 1647

Part III DETAILED ACTION

1. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1647.
2. Applicant's election of Group I, claims 1-10, 17-19, and 22 drawn to protein-Gal α 1,3Gal conjugates, in Paper No. 4, filed 4/24/02, is acknowledged.
3. Claims 11-16 and 20-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 4.
4. The IDS filed 8/27/01 will be considered by the Examiner with the next Office Action because the parent case containing the references was not available to the Examiner at the time of the first action on the merits.
5. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in the United Kingdom on 8/31/95. It is noted, however, that applicant has not filed a certified copy of the patent application as required by 35 U.S.C. 119(b).
6. Claims 4-10 and 17-19 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only and/or cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Art Unit: 1647

7. Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. This claim is an omnibus type claim.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 2-3 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for human proteins, does not reasonably provide enablement for proteins that do not cause an adverse immune response when present in humans or functional equivalents of human proteins. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The specification does not adequately describe or provide sufficient guidance or examples for proteins that do not cause an adverse immune response when present in humans or functional equivalents of human proteins. The unpredictability in the molecular biological protein art is high, and therefore the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved (*In re Fisher*, 166 USPQ 18). The disclosure does not teach how to make the genus of proteins that do not cause an adverse immune response when present in humans or functional equivalents of human proteins because of the unpredictability between a protein's structure and function (see *Rudinger*). The sub-genus of actual proteins of human origin encompassed by the claims is enabled because, in general,

Art Unit: 1647

same-species proteins, such as albumin, do not cause adverse immune responses between members of the same species, including humans. Functional equivalents, having no limitation as to specific structure, however, would produce an adverse immune response because although they may be functionally equivalent, the proteins encompassed can be structurally different (such as growth hormones between species), and it is the structural differences that bring about the adverse immunological responses, not the function of the proteins in question. No adequate guidance is provided by the teachings of the disclosure as to how to make the genus of functional equivalents of human proteins or proteins that do not cause adverse immune reactions due to the complexity of the protein arts (predicting structure from function and vice versa) and the complexity of the immune system.

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Art Unit: 1647

11. Claims 1 and 3 are rejected under 35 U.S.C. 102(e) as being anticipated by Good et al. ("Good"). Good discloses carbohydrate conjugates meeting the limitations of claims 1 and 3 (functional equivalent) (column 11, lines 20-31).

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claim 2 is rejected under 35 U.S.C. 103(a) as being obvious over Good in view of Pozansky. Good teaches conjugates as set forth above. Good does teach a protein that does not cause an adverse reaction in humans. Pozansky teaches conjugates with human albumin that do not cause adverse reactions (column 2, lines 49-59). The advantage of substituting human albumin for BSA is that the human albumin would be less likely to have an adverse immune response in humans than bovine serum albumin (BSA).

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (703) 308-6571. The examiner can normally be reached on Monday to Friday from 0930 to 1800. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached

Serial Number: 09/692,249

Page 6

Art Unit: 1647

on (703) 308-4623. The fax phone number for this Group is currently (703) 308-4242, but Applicant should confirm this by phoning the Examiner before faxing.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SG

Stephen Gucker

August 12, 2002

*Gary L. King
SPE, B.D. 1647*